



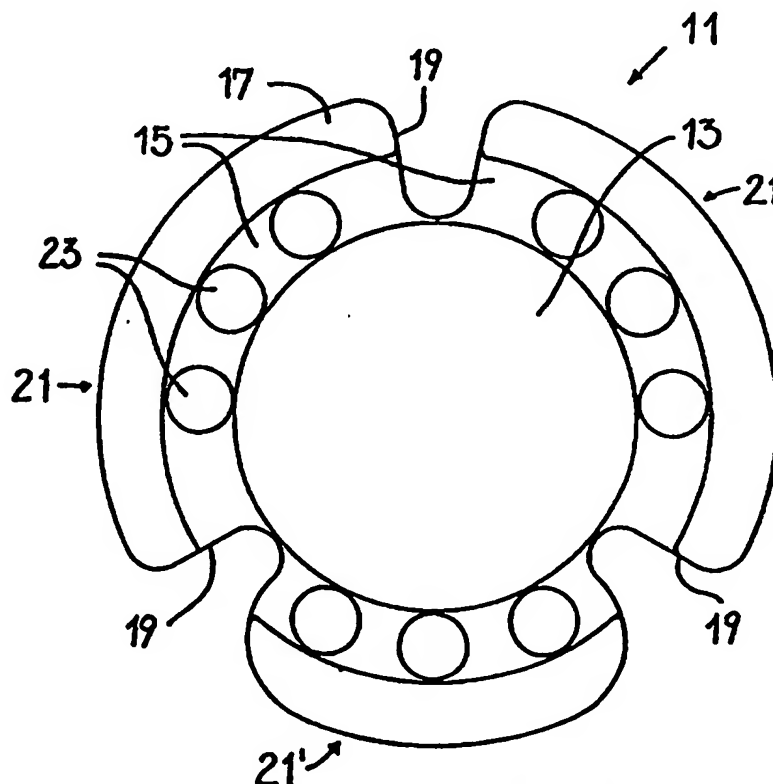
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/16		(11) International Publication Number: WO 97/43984
A1		(43) International Publication Date: 27 November 1997 (27.11.97)
(21) International Application Number: PCT/IB97/00567 (22) International Filing Date: 16 May 1997 (16.05.97) (30) Priority Data: 1255/96 17 May 1996 (17.05.96) CH (71)(72) Applicant and Inventor: PAYER, Helmut [AT/CH]; Plantaweg 12a, CH-7000 Chur (CH). (74) Agents: RIEDERER, Conrad, A. et al.; Bahnhofstrasse 10, CH- 7310 Bad Ragaz (CH).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: AN OCULAR IMPLANT

(57) Abstract

The invention relates to an ocular implant for insertion into the lens capsule of the eye, comprising a lens which is substantially non-deformable by the forces prevailing in the eye, and a haptic portion having an annular edge bead (17) and a forwardly bent annular intermediate region (15) which connects the edge bead (17) to the lens (13). One or more recesses (19) extend inwards from the periphery, and the intermediate region is constructed so as to be so elastically deformable that when centripetal pressure is exerted on the edge bead (17) there is substantially no deformation of the lens (13), but instead the lens (13) is moved axially relative to the edge bead (17).



BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

An ocular implant

The invention relates to an ocular implant for insertion into the lens capsule of the eye, comprising a lens which is substantially non-deformable by the forces prevailing in the eye, and a haptic portion connected to the lens.

CH 681687 discloses a plastic lens comprising a flexibly deformable lens member surrounded by a likewise elastically deformable force-transmitting part. The force-transmitting part has approximately the same thickness as the lens and comprises an edge region with two notches for facilitating the insertion of the plastic lens. The force-transmitting part is curved towards the rear, so that the lens has a plate-like shape.

The said plastic lens is based on the idea of using the centripetal forces occurring during the accommodation process to thicken the flexible lens member and thus increase the refractive power thereof.

One disadvantage of the disclosed plastic lens is its relatively large volume, which increases the difficulty of implantation through frontal capsulorhexis. Contrary to original hopes, the lens is non-foldable, because of its volume. This is probably the main reason why the lens has not become important in practice and has not even been produced as a prototype. Another disadvantage is that in the event of progressive fibrotic shrinkage of the lens capsule equator, the lens can be partly pressed through the

window in the front of the lens capsule and becomes partly spherical to the rear. As a result of the internal material flow, its refractive power increases. This is shown by increasing myopia, which increasingly incapacitates the patient.

US 4 994 082 discloses a substantially planar intra-ocular implant with a lens having a progressive refractive power and comprising a haptic portion. The disclosed implant, in a first exemplified embodiment, has the advantage that the contraction or relaxation of the ciliary muscle is transmitted by the haptic portion to the lens and is displaced at right angles to the optical axis. The focal point can be altered in dependence on the place where light passes through the lens. In a second exemplified embodiment the optical system comprises two lenses held by three pairs of arms constituting the haptic portion. When the ciliary muscle contracts, one pair of arms spread apart, so that the lenses move apart in the direction of the optical axis. By this means, the refractive power of the optical system can be varied. One disadvantage of the said implants is that they are relatively complicated and cannot be adapted to the accommodation capacity of individual patients. In the first embodiment also, there is a particularly serious risk of the front and the rear lens leaves sticking together.

WO-A-89/06520 describes a planar implant having a lens wherein the ciliary muscle alters the lens curvature and geometry. To this end a deformable central lens structure is provided and comprises two diaphragms which are welded together and form a chamber. The lens

is held by a ring structure comprising an inflatable ring. Since the lens and the ring are not inflated until after implantation by filling the chamber with viscous liquid, the implant can be inserted into the eye more easily. Since of course the lens is very easily deformable, the filled ring must ensure that the lens has an adequate yield stress. One disadvantage of the implant is that as fibrous degeneration of the lens-capsule equator increases, the front and rear walls of the lens become curved and, owing to the front capsule window and - after rear capsulotomy - also owing to the rear capsule opening acquire anterior curvature, resulting in incapacitating myopia.

SU 1553-109A describes a crystalline lens supported by a haptic portion formed with peripheral recesses. The lens and the haptic portion are curved, with radii of opposite signs. The implant is inserted so that when the ciliary muscle contracts the lens moves backwards, thus displacing the focal point to the rear (myopia-increasing effect). A disadvantage of the implant is that the front and the rear leaf of the lens capsule may stick together in the region of the recesses, which may result in formation of fibrotic tissue.

The object of the invention is to provide an ocular implant of the kind according to the preamble which substantially maintains the topography of the lens capsule and of the zonule of Zinn, thus avoiding post-operative injury to the eye through the implant. Another object is to improve long sight and near vision by means of the implant. If fibrotic shrinkage of the lens capsule occurs, the lens should not alter, particularly in refractive power or its position

relative to the retina, in a manner which increasingly incapacitates the eye.

To this end, in an implant according to the preamble, the haptic portion has an annular edge bead and a forwardly bent annular intermediate region which connects the edge bead to the lens; the haptic portion has one or more recesses extending inwards from the periphery; and the intermediate region is constructed so as to be elastically deformable so that when centripetal pressure is exerted on the edge bead there is substantially no deformation of the lens, but instead the lens is moved axially relative to the edge bead. The advantage of this is that the lens member can move forward under the centripetal pressure of the elastic equatorial ring of the natural lens capsule and makes near accommodation possible. The new plastic lens therefore makes advantageous use of the function, frequently still intact even in older persons, of the ciliary muscle, the fibrils of the zonule of Zinn and the elastic equatorial ring of the lens capsule which has a centripetal effect. This is a means of substantially improving the vision of patients with an inserted intra-ocular lens, so that frequently they have good vision, both distant and near, without additional glasses.

In contrast to the elastically deformable lens according to CH 681687, the invention does not increase myopia, even in the event of progressive fibrosis of the lens capsule, since the lens is practically non-deformable by the forces prevailing in the eye and consequently cannot be pressed through the window in the lens capsule. The remaining fibrotic ring in the

front wall of the capsule constitutes a barrier against forward movement of the optical system. It is therefore practically impossible for the patient to be subsequently incapacitated, as may still be the case with the known implant.

The haptic portion is constructed so as to be so elastic that under centripetal force it pushes the lens forward and can expand again when the centripetal force decreases. In the accommodation-free state it holds the lens capsule slightly extended, but during accommodation it can be compressed by the centripetal forces acting in the eye.

The permanent separation between the front and the rear capsule leaf is also important in preventing secondary cataract. This can be permanently ensured by the cap shape of the lens. Cell formation is also inhibited by the surface contact of the haptic portion and the optical system with the inner surface of the equatorial ring of the lens capsule and the remaining front capsule leaf, both of them exclusively representing the germinal zone for cell growth.

The cup shape acts as a spacer for the rear capsule and prevents the front side of the capsule leaf from sticking to the rear. The resulting permanent separation of the capsule leaves is an essential condition for maintaining the elastic forces which must operate during accommodation and de-accommodation. The prevention of secondary cataract as a result of the construction of the lens may be particularly important for replacement of the lens in a child's eye.

The annular edge bead or roll firmly supports and automatically centres the implant. The exterior of the bead preferably has a round cross-section. The positive effect of the edge bead is that it can prevent the formation of secondary cataract, since cell growth is prevented by abrasion and by surface contact (annular bead chafes). After an operation, the secondary cataract may occur in only three or four weeks. Previous experience in implantation shows that the proportion of secondary cataracts is particularly low.

The elastic intermediate ring, which is thinner (less material thickness) than the edge bead and the lens in the central region, has the advantage that in the event of extreme and possibly strong fibrosis of the lens capsule equator, the intermediate ring can warp, because the optical system cannot come out of the round window in the front capsule. Also there can be no incapacitating increase in refractive power through thickening of the lens, since the lens is substantially rigid under the forces prevailing in the eye.

The intra-ocular implant according to the invention, comprising an annular bead and having a cup shape, maintains the topography and the geometry of the lens capsule and of the corona ciliaris of the zonule fibrils and is thus the functioning end link in the chain of dynamic components of the accommodation apparatus, so that the remaining function of all the links (ciliary muscle, zonule fibres, elastic equatorial ring of the lens capsule) can be used for pseudo-accommodation.

Preferably the haptic portion is formed with two approximately opposite recesses. The two recesses make it easier for the periphery of the lens to reduce under centripetal force. Also the implant is particularly easy to fold, and this facilitates insertion through the elastic round window created by frontal capsulorhexis. Particularly advantageously, the haptic portion has three recesses. This embodiment has the advantage that the implant, which is folded during the implantation process, can unfold automatically and particularly easily after being released in the lens capsule. Another result of the edge bead is that the lens is automatically centred. In principle more than three recesses or only one recess can be provided.

Advantageously, two recesses are disposed with mirror symmetry at an angle of 120 to 150°, preferably 140°, to the recess at the front in the direction of insertion. The result is a narrower edge bead portion, which can form the tail during the implantation process. Advantageously, undercuts are formed at the ends of the edge beads at the front in the direction of insertion. This can further reduce the resistance of the intermediate region to peripheral reduction of the haptic portion. Since the edge bead forming the tail is not undercut, it cannot be trapped in the elastic front wall of the lens capsule when the implant is inserted through the round window. This is important, because delay or failure of the implantation process may injure the eye.

Preferably the implant is foldable. The folding axis advantageously extends through at least one recess in the case of a single fold. If there is a double fold,

at least one recess determines the direction of implantation. The double fold can result in a three-layer implant, the transverse diameter being reduced to little more than a third of the original diameter of the implant. The increase in thickness of the implant, folded in three layers, remains small, owing to the thinness of the intermediate ring. Consequently the width of the incision for implantation in the eye can be reduced to just 4 mm. Implantation is thus possible by the keyhole method, so that the radii of curvature of the cornea are not adversely altered by the operation.

Advantageously, the intermediate region has a number of spaced-apart recesses which facilitate elastic deformation thereof. Alternatively the recesses can be used for improved suction removal of the visco-elastic liquid used during implantation. The perforations can e.g. be circular. The result is a spoke structure. The perforations may also be rectangular or trapezoidal. However, optimum deformability of the intermediate region can be obtained simply by suitable choice of the elastic properties of the plastic used and of the thickness thereof.

Advantageously, the intermediate region is bent forward between about 5° and 15°, preferably about 10°, relative to a plane at right angles to the optical axis, so that during accommodation the direction of movement of the optically active lens forwards is determined. The implant is well supported by the forwardly bent intermediate region in the outer periphery of the lens capsule. Fibrosis can be prevented by the large surface contact between the peripheral edge bead and

the inner surface of the lens capsule equator, and the contact between the edge region of the lens and the edge of the round window in the front capsule. Excessive bending, however, is usually undesired, because this means a risk of chafing the rear pigment leaf of the iris at the edge of the front round window (capsulorhexis edge), which may trigger a pigment dispersion syndrome.

In a particularly advantageous embodiment, the lens has a central zone of increased refractive power or is designed as a multi-focal lens. The optimum automatic centring of the implant enables the near vision to be further assisted by central increase of the power of the lens to the dioptric power necessary for reading. Preferably, the zone of increased refractive power is an approximately circular lens, e.g. from about 0.8 to 2 mm, preferably about 1 mm in diameter. Since the zone of increased refractive power is reduced in size to a minimum, there is no or only inappreciable interference with long sight, which is made possible by the strength of the surrounding lens. During near accommodation the pupil contracts, with the necessary adjustment of convergence of the two eyes on the near object. When the pupil is narrow the path of rays is through the centrally increased-power lens, whereas in the case of accommodation to distance the pupil widens and long sight is possible via the surrounding lens having the lower dioptric power. In the physiology of accommodation this means that static accommodation occurs in addition to the dynamic process of accommodation via the more powerful central portion of the lens.

In principle the optical system can be a diffractive lens or a multi-focal lens. It can e.g. comprise concentric rings having different refractive indexes.

The invention also relates to a folding forceps for folding and holding the lens and having two gripping parts movable in opposite directions, concave as seen from above, and adapted to come into contact at front and rear when in the closed state. Advantageously the gripping parts have an oval shape and each have a recess.

Exemplified embodiments of the invention will now be described with reference to the drawings, in which:

Fig. 1a is a plan view of a first exemplified embodiment of an implant according to the invention having three recesses at the peripheral edge;

Fig. 1b shows the first exemplified embodiment in section;

Fig. 2a shows a second embodiment comprising an additional central lens of higher refractive power and wherein the recesses are partly undercut, likewise in plan view;

Fig. 2b shows the second exemplified embodiment in section;

Fig. 3 shows a third exemplified embodiment of an implant with pairs of opposite recesses and notches in the peripheral edge;

Fig. 4 is a partial cross-section through an eye with a lens fixed in it;

Fig. 5a is a perspective view of a folding forceps for folding the implant;

Fig. 5b is a plan view of the folding forceps in Fig. 5a;

Fig. 6a is a side view of an implant held with the folding forceps;

Fig. 6b shows the same in cross-section;

Fig. 7 shows a folding forceps with asymmetrical branches for folding an implant in three layers, and

Fig. 8 diagrammatically from top to bottom shows the chronological sequence during folding of the implant.

Implants 11, 11' preferably in one piece of suitable plastic, shown in Figs. 1 and 2, comprise a central lens 13 which behaves substantially rigidly after insertion of the implant, i.e. the lense does not change its focal power due to applied centripetal pressure during accomodation, and a haptic portion which surrounds the lens 13 and comprises a peripheral edge bead 17 and an intermediate region 15 which connects the edge bead 17 to the lens 13. The intermediate region 15 is bent forwards, e.g. at an angle of 8 to 12°, preferably about 10°.

The haptic portion is interrupted by three recesses 19 and 20, 20' respectively, resulting in three edge bead portions 21, 21' respectively. The recesses 19 and 20, 20' respectively extend almost to the lens 13 or can be made less deep. By means of the recesses 19, 20 and 20' the periphery or diameter of the haptic portion can be reduced by the centripetal pressure of the ciliary muscle of the eye, with the result that the lens 13 is pushed forward but without being pressed out of the round window in the lens capsule.

The intermediate region 15 has a number of spaced-apart circular recesses 23 which increase the flexibility of the intermediate region 15. In principle the intermediate region 15 should have an elasticity such that under centripetal pressure it can push the lens forward and can expand again when the centripetal pressure decreases. In the optimum case the intermediate region is sufficiently elastic for the intermediate region 15 to bulge forward or backward if there is severe fibrosis of the lens capsule.

The circular recesses 23 result in a spoke structure which ensures the previously-mentioned favourable properties of the intermediate region 15. Other shapes of recesses, e.g. rectangular or trapezoidal, are also possible. The recesses 23 enable the visco-elastic liquid used during the operation to be quickly and completely removed by suction.

Preferably, undercuts 25, 25' are formed adjoining the ends of the edge bead portions 21 at the front in the direction of insertion, thus reducing the resistance to

peripheral reduction of the haptic portion under centripetal pressure.

Advantageously, the rear annular portion 21' in the direction of insertion is without such undercuts, to prevent the implant from catching when inserted into the lens capsule.

In the particularly preferred embodiments in Figs. 1 and 2, two recesses 19 and 20, 20' respectively are disposed with mirror symmetry at an angle of approximately 140° to the recess 19, 20 respectively at the front in the direction of insertion. The result is a somewhat narrower edge bead portion 21' which facilitates insertion and unfolding of the implant inserted into the lens capsule. The implant, held by a special folding forceps, can be brought by gentle pressure through the 4 mm section of the cornea into the anterior chamber of the eye and slides like a fish, still folded over about two-thirds of its size, through the elastic round window, created by capsulorhexis, in the front wall of the lens capsule unfolded with visco-elastic substance. When the folding forceps opens, the implant automatically unfolds and centres itself.

Fig. 3 shows an exemplified embodiment which differs from the previous examples in that instead of three recesses there are only two, having the reference 20. The recesses 20 are diametrically opposite one another. In addition, two likewise diametrically opposite smaller recesses or notches 24 are formed in the edge bead 17. These facilitate implantation when there is only one fold. The recesses 20 and notches 24 are offset from one another by 90° respectively.

Fig. 4 shows only the portion of the human eye which adjoins the cornea 29. The iris 31 is behind the cornea and the lens capsule 33 is behind the iris. The lens 13 is inserted into the lens capsule 32 with the rear leaf 33 and the front leaf 35 and stretches it to some extent. In the state of near accommodation the lens 13 is pushed forward by the centripetal force of the elastic ciliary ring (Fig. 4, top half). The round window made in the front lens leaf 35 is marked 37.

The folding forceps 41 has two gripping parts 43 movable in opposite directions, gripping in pairs, concave as seen from above, and touching at front and rear when in the closed state (Fig. 5b). The gripping parts are oval, each with an elongate recess 45 (Fig. 5a). When the elastic implant is compressed during the folding process, it swells into the recesses 45 and is thus held firmly during the implantation process (Fig. 6).

Another embodiment of a folding forceps or tweezers 51 has two gripper parts or branches 53, 55 which in cross-section are approximately semicircular or U-shaped. The branch 53 has a radius r_1 , and the branch 55 has a radius r_2 , the latter being somewhat greater than the radius r_1 . Stops 57 ensure that the branches 53, 55 of the folding forceps 51 can be pressed together only to the extent where the retaining parts 59 of a gripping and implantation folding forceps (not shown in further detail) can engage between the branches 53 and 55 (Fig. 8). A spreading stop 61 ensures that the branches can be spreaded just to a distance which is about 3 to 4 mm smaller than the

diameter of the unfolded implant. For gripping the implant the same must therefore be pre-folded at two opposite sides and uncontrolled wrapping of the implant can thus be prevented.

When the implant 11, 11' or 11'' is gripped by the folding forceps, the edge regions of the haptic portion under the lens are folded inwards (Fig. 8). The edge region gripped by the branch having the larger radius r_2 comes to rest under the edge region gripped by the other branch. The result in the middle is three layers, and the diameter of the folded implant is only about one-third of the original implant when not folded.

The embodiment of an implant 11 as shown in Fig. 1 has an outer diameter of 9.8 to 10 mm. The lens 13 has a diameter of 5.8 mm and the circular recesses 23 have a diameter of 1 mm. The intermediate region has a thickness of only about 0.2 mm. In the central region the lens, depending on the dioptric power, has a thickness of about 0.7 to about 1.35 mm (0.9 mm in the example shown). The peripheral width of the recesses is about 0.8 mm each.

The exemplified embodiment shown in Fig. 2 has a central lens 28 of increased refractive power, which improves near sight. Since the miotic convergence reaction of the pupils is retained during near accommodation of the two eyes and since older people frequently suffer from senile miosis, the eye acquires depth of focus like a pinhole camera, by screening out extra-axial rays (stenopaic principle).

The lens 13 is made of a bio-compatible material. Very good results have been obtained with a straight-chain high-molecular acrylic copolymer, e.g. of methyl acrylate and 2-hydroxyethyl methacrylate. Cross-linking agents, UV absorbers and starters are preferably fully incorporated in the polymer matrix, preventing any leaching. A particularly suitable material of the said kind is obtainable from Messrs Morcher GmbH, Stuttgart.

In the implantation process, a round window 37 is first traced in the front capsule wall 35, with a circular central capsulorhexis, and the lens capsule 32 is emptied by removing the cloudy lens masses. In a perfect operation, the lens capsule 32 and the zonule of Zinn are undamaged, thus avoiding injury to the corneal endothelium, which would have serious consequences. The implant is then folded, using the special folding forceps 41 or 51, so that the narrower edge bead portion 21' is at the rear in the direction of insertion, as shown by the broken line 27 in Fig. 2. The implant can then be partly inserted into the lens capsule 32, by stretching the round window, and can automatically slide after release, when it gently unfolds and is automatically centred.

If the implant is folded in three layers by the folding forceps 51 during the implantation process, the advantage will be that when held by the retaining parts 59 of the folding forceps, the implant can be inserted through the incision without the operator having to make a manual rotation through 90°. This greatly facilitates implantation and also permits insertion

through a smaller incision than in the conventional method.

The compression force for provoking an axial displacement of the lense have been determined experimentally according to ISO/DIS 11979-3 by using a miniature material tester (Vitrodyne V-200L) and a Laser scan micrometer from Keyence with a resolution of ± 0.001 mm. The measurements were conducted in an aqueous 1% NaCl-solution at 35 °C. The force necessary for provoking an axial displacement of the lense of 0.1 mm ranged between 0.85 mN and 0.65 mN per 0.1 mm displacement (see table).

displacement in mm	force (in mN)
0.1 - 0.5	0.85
0.5 - 1.5	0.65

The invention is not restricted to the embodiments shown. For example the zones of increased refractive power in Figs. 2a, 2b can be omitted or another kind of lens, such as a multi-focal lens, can be used. The important thing is that the haptic portion has at least one recess extending inwards from the periphery, the intermediate region being made elastically deformable so that when centripetal force is exerted on the edge bead there is practically no deformation of the lens, and instead the lens moves axially relative to the edge bead, i.e. forwards in the direction of the optical axis.

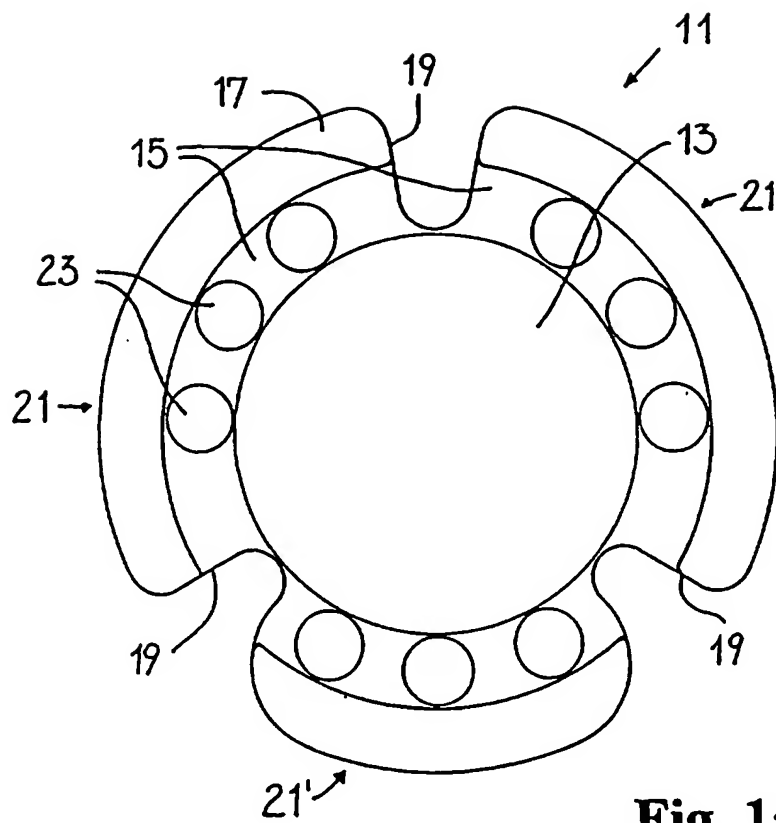
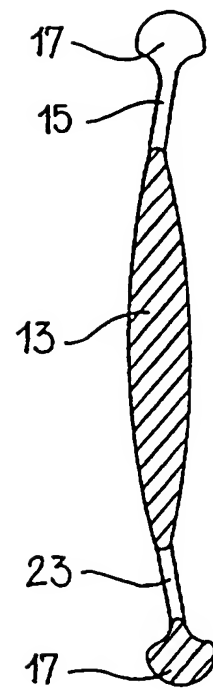
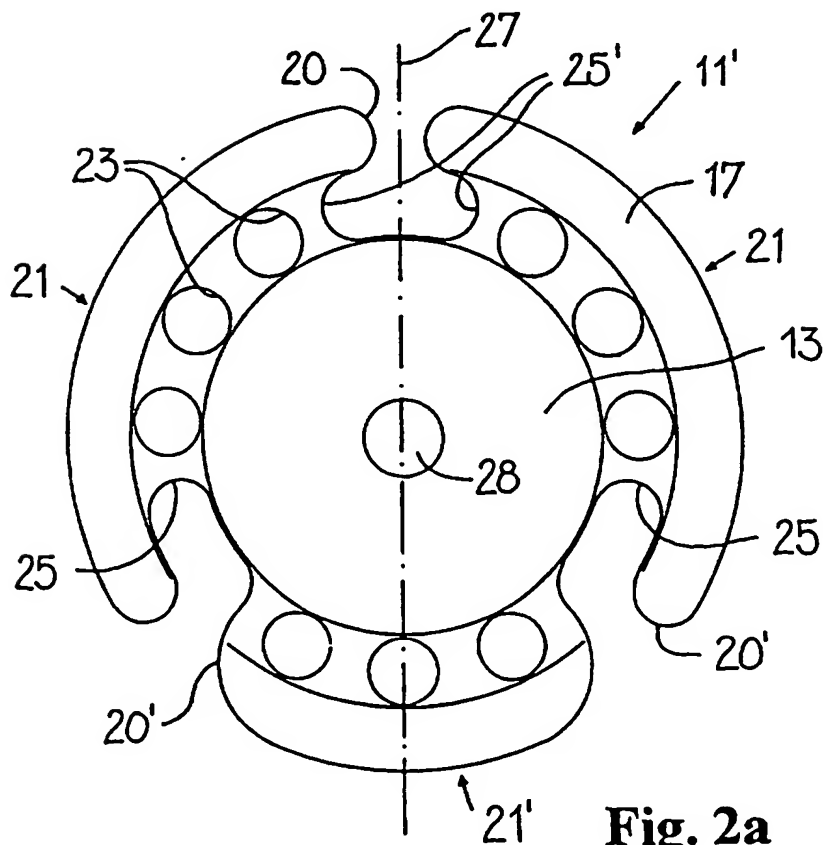
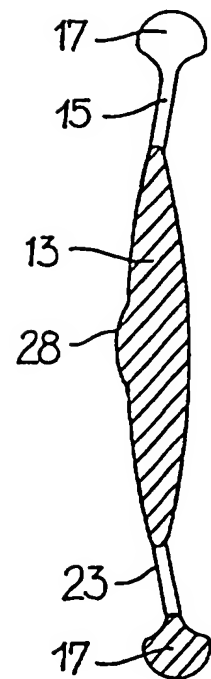
Claims

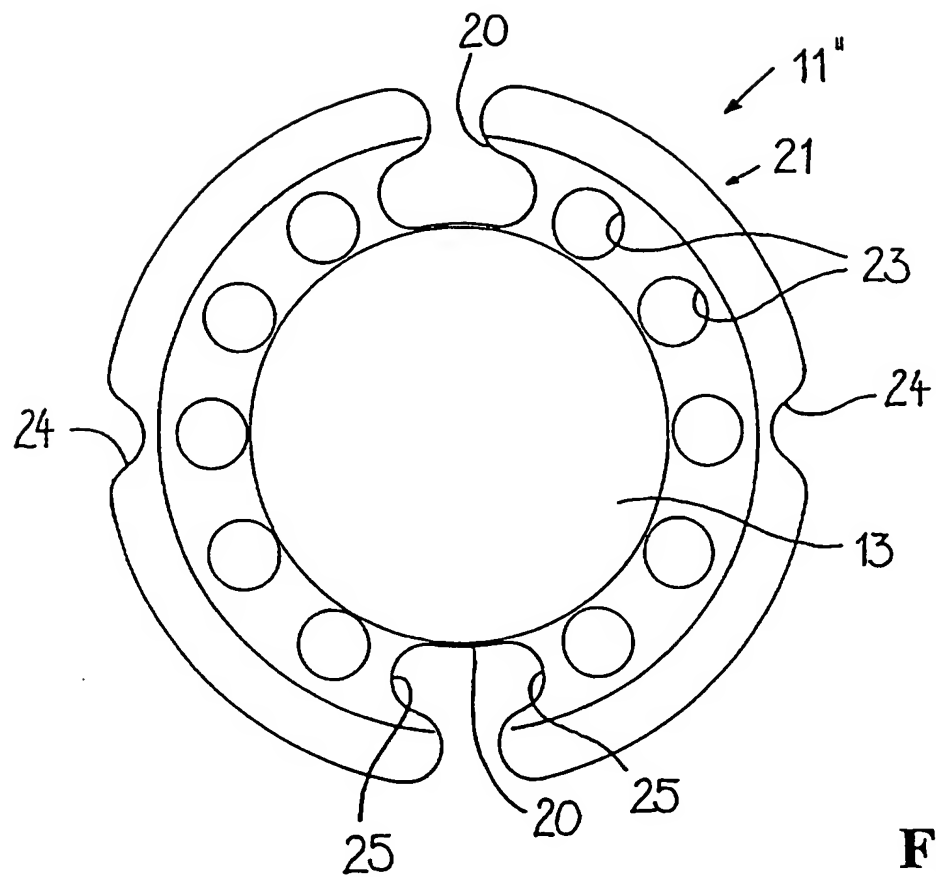
1. An ocular implant for insertion into the lens capsule of the eye, comprising a lens (13) which is substantially non-deformable by the forces prevailing in the eye, and a haptic portion (15, 17) connected to the lens (13), characterised in that the haptic portion (15, 17) has an annular edge bead (17) and a forwardly bent annular intermediate region (15) which connects the edge bead (17) to the lens (13), in that the haptic portion has one or more recesses (19) extending inwards from the periphery, and in that the intermediate region is constructed so as to be so elastically deformable that when centripetal pressure is exerted on the edge bead (17) there is substantially no deformation of the lens (13), but instead the lens (13) is moved axially relative to the edge bead (17).
2. An implant according to claim 1, characterised in that at least two approximately opposite recesses (19) are formed on the haptic portion.
3. An implant according to claim 1 or 2, characterised in that the haptic portion has three recesses (19).
4. An implant according to claim 3, characterised in that two recesses (19) are disposed with mirror symmetry at an angle of 120 to 150°, preferably 140°, to the recess at the front in the direction of insertion.

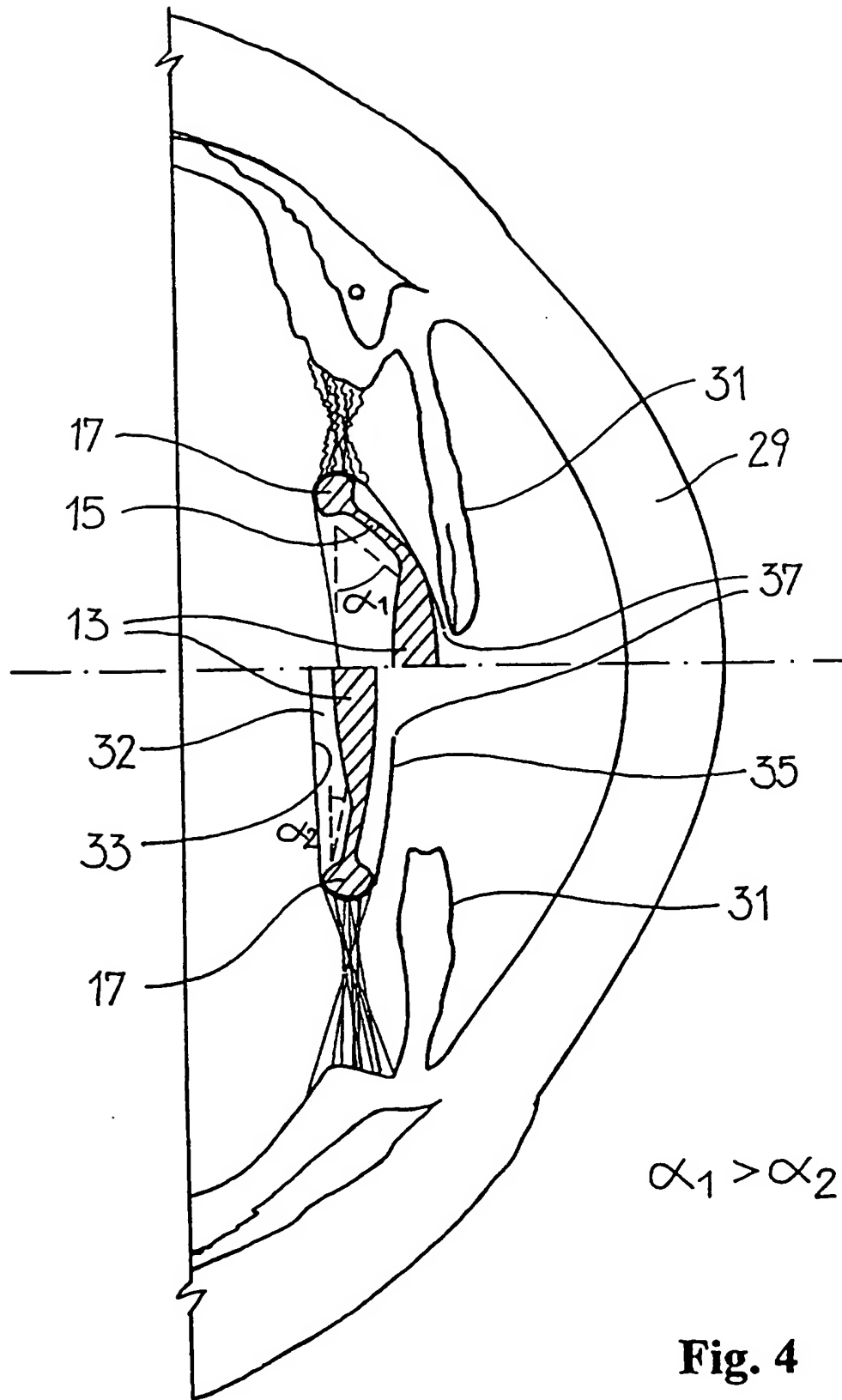
5. An implant according to claim 3 or 4, characterised in that undercuts (25, 25') are formed at the ends of the beads (17) at the front in the direction of insertion.
6. An implant according to any of claims 1 to 5, characterised in that the implant is foldable.
7. An implant according to any of claims 1 to 6, characterised in that the folding axis extends through at least one recess (19).
8. An implant according to any one of claims 1 to 7, characterised in that the intermediate region (15) has a number of spaced-apart recesses.
9. An implant according to any of claims 1 to 8, characterised in that the intermediate region (15), as a result of the recesses, is equivalent to a spoke structure.
10. An implant according to any of claims 1 to 9, characterised in that the haptic portion is bent forwards between about 5° and 15° , preferably about 10° , relative to a plane at right angles to the optical axis.
11. An implant according to any of claims 1 to 10, characterised in that the lens (13) has a central zone (28) of increased refractive power, i.e. is constructed as a bifocal lens (13) or as a multifocal lens.

12. An implant according to claim 11, characterised in that the zone of increased refractive power is an approximately circular lens (28), e.g. about 0.8 to 2 mm in diameter, preferably about 1 mm.
13. An implant according to any of claims 1 to 13, characterised in that the lens body is biconvex and the haptic portion is substantially circular.
14. An implant according to any of claims 1 to 13, characterised in that the implant consists mainly of a methyl acrylate and 2-hydroxyethyl methacrylate copolymer.
15. A folding forceps (14) for folding and holding an intra-ocular implant (13), characterised by two gripping parts (43) which are movable in opposite directions to one another, concave as seen from above, and can come into contact front and back when in the closed state.
16. A folding forceps according to claim 15, characterised in that the gripping parts (43) are oval and have a preferably oval recess (45).
17. A folding forceps for folding an intra-ocular implant (13), characterised by two branches (53, 54) which are movable in opposite directions to one another and are approximately semi-circular in cross-section, their concave parts facing one another and the radius of one branch (51) being less than the radius of the other branch (53).

18. A folding forceps according to claim 17, characterised in that at least one stop (57) is provided on the branches (53, 55) and ensures that the branches (53, 55) remain a given distance apart when in the holding position.
19. A folding forceps according to claim 17 or 18, characterised in that a spreading stop (61) is provided.

**Fig. 1a****Fig. 1b****Fig. 2a****Fig. 2b**

**Fig. 3**

**Fig. 4**

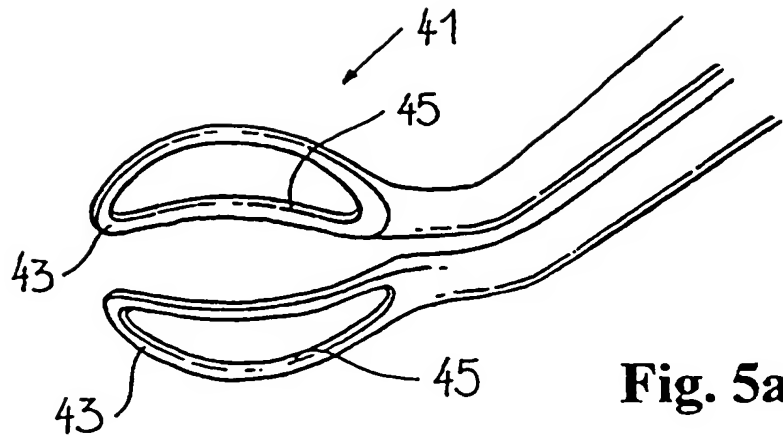


Fig. 5a

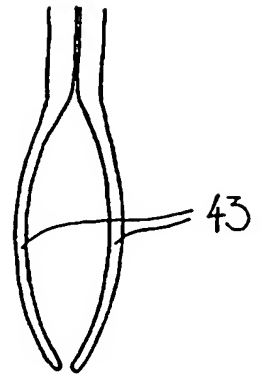


Fig. 5b

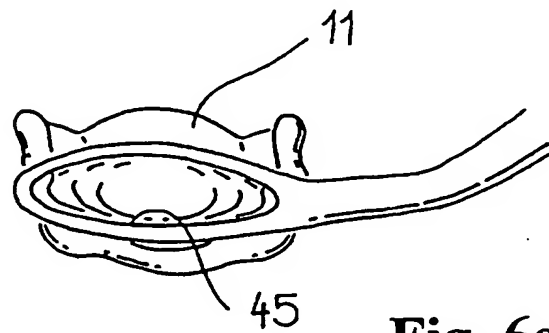


Fig. 6a

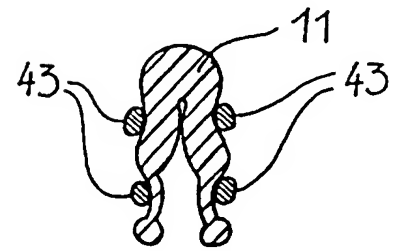


Fig. 6b

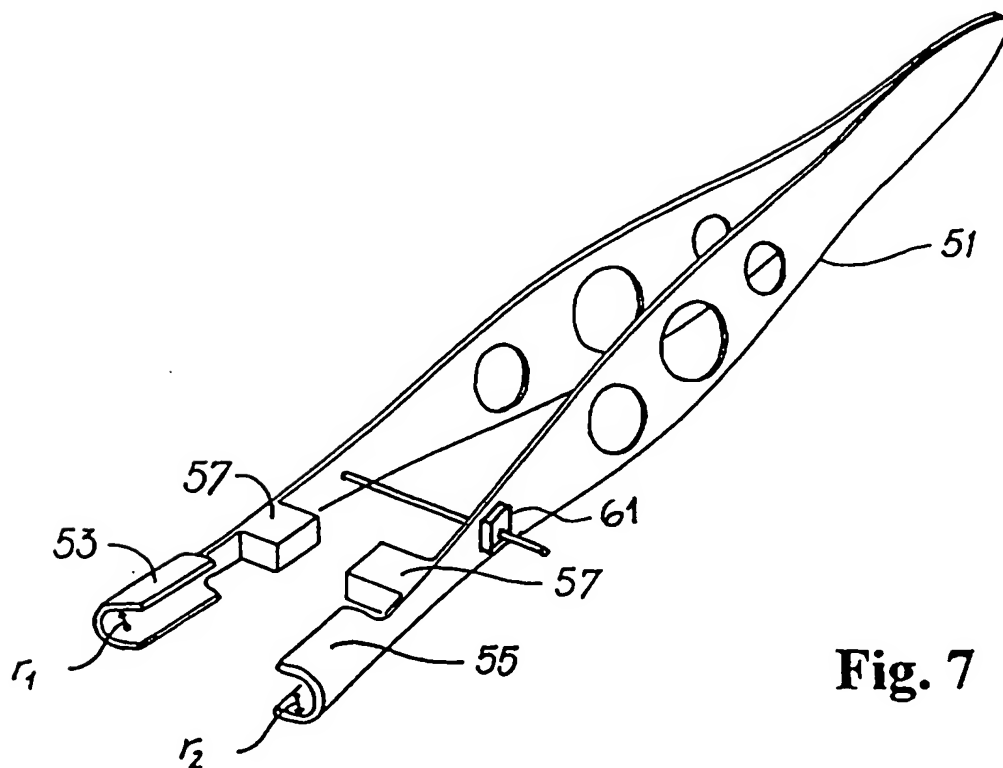
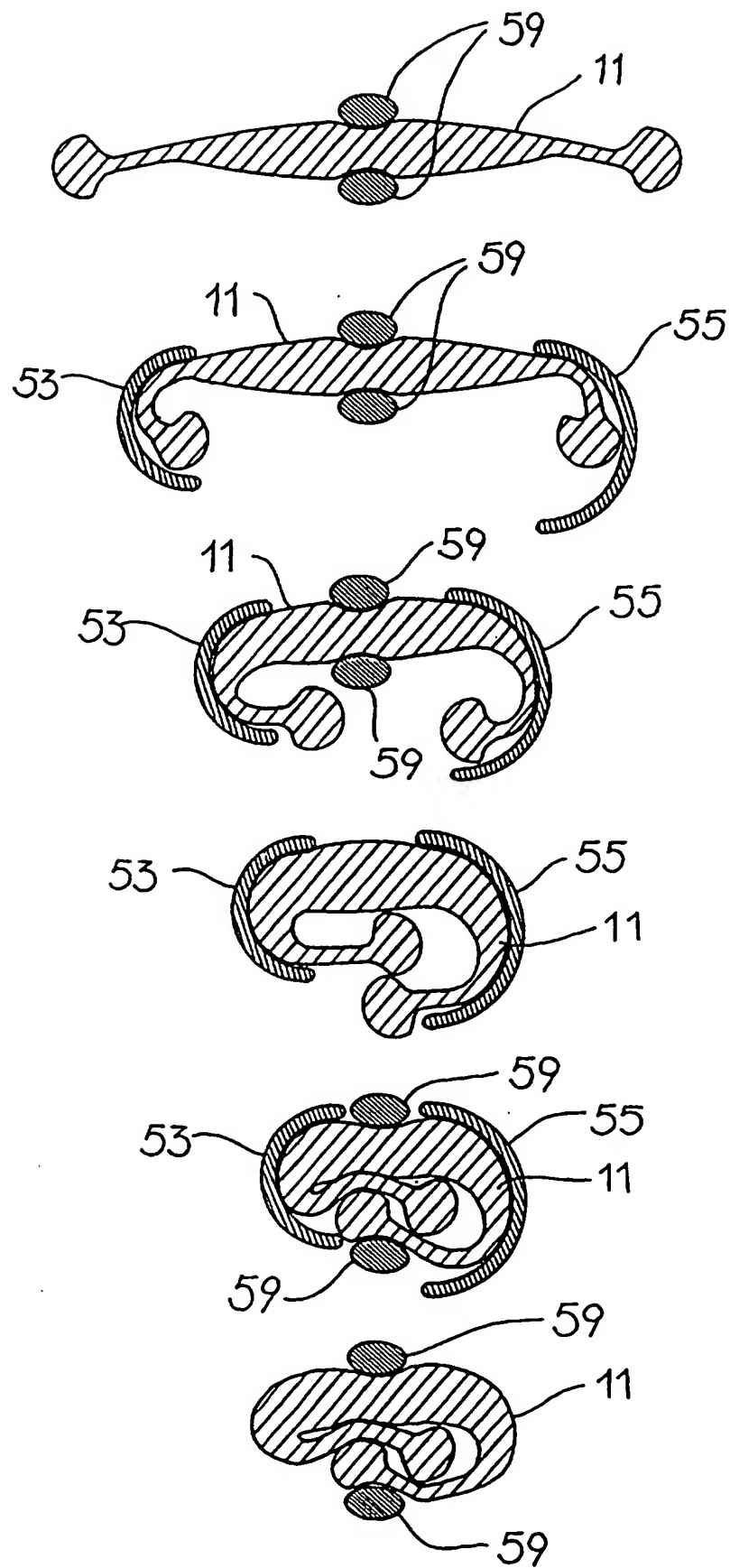


Fig. 7

**Fig. 8**

INTERNATIONAL SEARCH REPORT

Internat. Application No

PCT/IB 97/00567

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 994 082 A (W.D. RICHARDS ET AL.) 19 February 1991 cited in the application	1-5,13
A	see figures 1-4 ---	8
X	WO 89 06520 A (G. HORN ET AL.) 27 July 1989 cited in the application	1-4,6-9, 13
Y	see the whole document ---	11,12,14
Y	US 5 026 396 A (J.J. DARIN) 25 June 1991 see column 3, line 52 - line 54; figures 1-6	11,12 1,6,13
A	---	
Y	EP 0 492 126 A (AMERICAN CYANAMID COMPANY) 1 July 1992 see abstract ---	14

	-/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

& document member of the same patent family

Date of the actual completion of the international search

2 July 1997

Date of mailing of the international search report

30. 09. 97

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

WOLF C.

INTERNATIONAL SEARCH REPORT

Internat. Application No.

PCT/IB 97/00567

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DATABASE WPI Section PQ, Week 9044 Derwent Publications Ltd., London, GB; Class P, AN 90-333114 XP002021132 & SU 1 553 109 A (EYE DISEASE RES, INST.) cited in the application see abstract</p> <p>---</p>	1-4,8-10
A	<p>US 4 878 912 A (L.D. CASTLEMAN) 7 November 1989 see abstract; figures 1-4</p> <p>---</p>	1,2,6-8, 10,13
A	<p>GB 2 151 371 A (CESKOSLOVENSKA AKADEMIE) 17 July 1985 see the whole document</p> <p>---</p>	1,6,8, 10,13,14
A	<p>EP 0 064 770 A (INPROHOLD ESTABLISHMENT) 17 November 1982 see abstract; figures 1-4</p> <p>---</p>	1,6,8,9, 13
A	<p>CH 681 687 A (H. PAYER) 14 May 1993 cited in the application</p> <p>-----</p>	

INTERNATIONAL SEARCH REPORT

Int .tional application No.

PCT/ IB 97/ 00567

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. Claims : 1-14
An acular implant.
2. Claims : 15-19
A folding forceps.

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-14

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat'l Application No

PCT/IB 97/00567

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4994082 A	19-02-91	NONE	
WO 8906520 A	27-07-89	US 4888012 A EP 0397741 A JP 7500255 T	19-12-89 22-11-90 12-01-95
US 5026396 A	25-06-91	NONE	
EP 492126 A	01-07-92	US 5217491 A AU 649758 B AU 9005991 A CA 2058350 A JP 4295353 A US 5326506 A	08-06-93 02-06-94 02-07-92 28-06-92 20-10-92 05-07-94
US 4878912 A	07-11-89	NONE	
GB 2151371 A	17-07-85	CS 8309329 A CA 1264502 A DE 3445364 A FR 2556211 A JP 1791020 C JP 4080699 B JP 60190949 A US 4846832 A	16-12-85 23-01-90 13-06-85 14-06-85 29-09-93 21-12-92 28-09-85 11-07-89
EP 64770 A	17-11-82	DE 3119002 A US 4424597 A	02-12-82 10-01-84
CH 681687 A	14-05-93	NONE	

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ **BLACK BORDERS**

☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

☐ **FADED TEXT OR DRAWING**

☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**

☐ **SKEWED/SLANTED IMAGES**

☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.